

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BAUSCH & LOMB INCORPORATED and	:	
PF CONSUMER HEALTHCARE 1 LLC,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	C.A. No. 20-1463-LPS
	:	
SBH HOLDINGS LLC,	:	
	:	
Defendant.	:	

Jack B. Blumenfeld and Derek J. Fahnestock, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, DE

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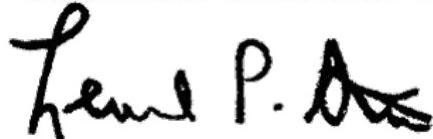
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MEMORANDUM OPINION

March 23, 2022
Wilmington, Delaware



Paul P. Stark
STARK, U.S. Circuit Judge:

Pending before the Court is Defendant SBH Holdings LLC's ("Defendant" or "SBH") motion to dismiss Plaintiffs Bausch & Lomb Incorporated and PF consumer Healthcare 1 LLC's ("Plaintiffs" or "B&L") complaint (D.I. 1), filed pursuant to Federal Rule of Civil Procedure 12(b)(6) or, in the alternative, request for a more definite statement pursuant to Rule 12(e) (D.I. 8). For the reasons set forth below, the Court will deny Defendant's motion to dismiss and its alternative request for a more definite statement.

I. BACKGROUND

On June 30, 2020, Plaintiffs sued Defendant in the U.S. District Court for the Western District of New York, alleging that Defendant infringed U.S. Patent Nos. 6,660,297 (the "'297 patent") and 8,603,522 (the "'522 patent"). (*Bausch & Lomb Inc. v. SBH Holdings LLC*, C.A. No. 6:20-cv-06451 (W.D.N.Y.) (the "W.D.N.Y. Action") D.I. 1 ¶¶ 8-32) On October 1, 2020, Defendant filed a motion to dismiss for improper venue pursuant to Rule 12(b)(3). (W.D.N.Y. Action D.I. 8) On November 2, 2020, Plaintiffs voluntarily dismissed the W.D.N.Y. Action pursuant to Rule 41(a)(1)(A)(i). (W.D.N.Y. Action D.I. 11)

On October 28, 2020, Plaintiffs brought the instant action against Defendant for the same patent infringement cause of action, alleging that Defendant infringed the '297 and the '522 patents (the "patents-in-suit") by making, using, importing, offering to sell, or selling MacularProtect® AREDS 2 and MacularProtect Complete® AREDS 2 (the "MacularProtect® AREDS 2 products"). (See D.I. 1 ¶¶ 15-17, 28-30) The patents-in-suit claim a formulation dosage of vitamin C, vitamin E, vitamin A in the form of beta-carotene (substituted or supplemented with lutein, zeaxanthine, or a combination thereof), zinc, and copper, as well as methods for manufacturing the dosage form and methods for administering the dosage form.

(See D.I. 13 at 3; *see also* '297 patent, cls. 1-3, 19, 25, 26, 31; '522 patent, cls. 1, 8, 11, 16) The compositions of the claimed dosage form are expressed both in absolute amounts and in relation to the U.S. recommended dietary allowance (“RDA”).

II. LEGAL STANDARDS

A. Rule 12(b)(6)

Evaluating a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) requires the Court to accept as true all material allegations of the complaint. *See Spruill v. Gillis*, 372 F.3d 218, 223 (3d Cir. 2004). “The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims.” *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997) (internal quotation marks omitted). Thus, the Court may grant such a motion to dismiss only if, after “accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, plaintiff is not entitled to relief.” *Maio v. Aetna, Inc.*, 221 F.3d 472, 481-82 (3d Cir. 2000) (internal quotation marks omitted).

However, “[t]o survive a motion to dismiss, a civil plaintiff must allege facts that ‘raise a right to relief above the speculative level on the assumption that the allegations in the complaint are true (even if doubtful in fact).’” *Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). A claim is facially plausible “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). At bottom, “[t]he complaint must state enough facts to raise a reasonable expectation that discovery will reveal evidence of [each] necessary element” of a plaintiff’s claim.

Wilkerson v. New Media Tech. Charter School Inc., 522 F.3d 315, 321 (3d Cir. 2008) (internal quotation marks omitted).

The Court is not obligated to accept as true “bald assertions,” *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) (internal quotation marks omitted), “unsupported conclusions and unwarranted inferences,” *Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997), or allegations that are “self-evidently false,” *Nami v. Fauver*, 82 F.3d 63, 69 (3d Cir. 1996).

B. Rule 12(e)

Federal Rule of Civil Procedure 12(e) allows a party to move for a more definite statement when a pleading is “so vague or ambiguous that the party cannot reasonably be required to frame a responsive pleading.” *Schaedler v. Reading Eagle Publ’n, Inc.*, 370 F.2d 795, 798 (3d Cir. 1967). “The decision whether to grant or deny a defendant’s motion for a more definite statement rests within the sound discretion of the court.” *Holmes v. Colonial Sch. Dist.*, 2010 WL 4918721, at *1 (D. Del. Nov. 24, 2010). Motions for a more definite statement are generally viewed with disfavor, particularly “where the information sought by the motion could easily be obtained by discovery.” *CFMT, Inc. v. Yield Up Intern. Corp.*, 1996 WL 33140642, at *1 (D. Del. Apr. 5, 1996).

III. DISCUSSION

A. Motion To Dismiss

Defendant first contends that Plaintiffs fail to plead facts sufficient to state a plausible patent infringement claim, insisting that the complaint fails to “identify how the patent claims read on [D]efendant’s products.” (D.I. 9 at 14) In the Court’s view, the facts pled in the complaint plausibly state an infringement claim.

A complaint must include sufficient facts to “place the alleged infringer on notice of what activity . . . is being accused of infringement.” *Bot M8 LLC v. Sony Corp. of Am.*, 4 F.4th 1342, 1352 (Fed. Cir. 2021) (internal quotation marks omitted). Therefore, a plaintiff cannot assert a plausible infringement claim by “reciting the claim elements and merely concluding that the accused product has those elements.” *Id.* at 1353. However, a plaintiff is not required to “plead facts establishing that each element of an asserted claim is met.” *Nalco Co. v. Chem-Mod, LLC*, 883 F.3d 1337, 1350 (Fed. Cir. 2018). The level of detail required for the complaint varies “depending upon a number of factors, including the complexity of the technology, the materiality of any given element to practicing the asserted claim(s), and the nature of the allegedly infringing device.” *Bot M8*, 4 F.4th at 1353.

In this case, Plaintiffs allege the following facts to support their infringement claims:

SBH is making, using, importing, offering to sell, or selling compositions containing a formulation of lutein, zeaxanthin, vitamins C and E, zinc, and copper, that are specifically described and claimed in the [patents-in-suit], including but not limited to SBH’s MacularProtect® AREDS 2 and MacularProtect Complete® AREDS 2 products (the “MacularProtect® AREDS 2 products”). SBH is making, using, importing, offering to sell, or selling such compositions for the use in treating or preventing age-related eye disease or for maintaining or preserving eye health or vision, which infringe the claims of the [patents-in-suit].

On information and belief, SBH is selling, offering for sale and/or importing compositions with instructions for use and promotions that cause and induce the user to infringe the claims in the ’297 Patent, including but not limited to SBH’s MacularProtect® AREDS 2 products. SBH is doing so with knowledge of the [patents-in-suit] and with specific intent that its customers will infringe the [patents-in-suit].

On information and belief, SBH is selling, offering for sale and/or importing components or materials, knowing the same to be especially made or especially adapted for use in an infringement of the [patents-in-suit].

(D.I. 1 ¶¶ 15-17, 28-30)

With respect to direct infringement, Plaintiffs have identified the accused products (“the MacularProtect® AREDS 2 products”), described the compositions of the accused products (“a formulation of lutein, zeaxanthin, vitamins C and E, zinc, and copper”), and alleged that the compositions were infringing because they contain a formulation disclosed and claimed in the patents-in-suit. (*See id.* ¶¶ 15, 28) Plaintiffs also attached the patents-in-suit to the complaint. (*Id.* Exs. A-C) Considering that the technology does not appear to be complex and that Plaintiffs’ infringement theory is straightforward, these factual allegations are sufficient to place Defendant on notice of the nature of the accused infringement. *See Disc Disease Sols. Inc. v. VGH Sols., Inc.*, 888 F.3d 1256, 1260 (Fed. Cir. 2018) (finding plaintiff’s infringement allegations sufficient when asserted patent “involves a simple technology” and complaint alleges that specifically named accused products meet “each and every element of at least one claim” of asserted patent); *see also, e.g., NNCrystal US Corp. v. Nanosys, Inc.*, 2020 WL 616307, at *3 (D. Del. Feb. 10, 2020); *Encoditech LLC v. Qardio, Inc.*, 2019 WL 2526725, at *6 (D. Del. June 19, 2019).¹

¹ Defendant directs the Court to *Golden v. Apple Inc.*, 819 F. App’x 930 (Fed. Cir. 2020). (*See D.I. 9 at 14-15*) In *Golden*, 819 F. App’x at 931, as the Federal Circuit pointed out, “[t]he complaint itself offers only vague generalities and block quotes of statutes, cases and treatises, but nowhere points us to any nonfrivolous allegations of infringement of any claim by any actual product made, used, or sold by any defendant.” The complaint here is not similarly deficient, as the Court has explained.

In *Bot M8*, which was decided after the briefing was completed, the Federal Circuit affirmed the district court’s finding that the plaintiff failed to state a claim because the allegations that the authentication program is located on the PS4 motherboard were “**inconsistent** with and contradict infringement,” as the asserted claim required that the authentication program be stored “separately from the motherboard.” *See Bot M8*, 4 F.4th at 1354. In this case, Defendant does not contend, nor does the Court find, that the complaint presents any similar inconsistency or contradiction.

Defendant's motion does not separately address indirect infringement. With respect to indirect infringement, Plaintiffs allege that using the compositions contained in the accused products in a specific way infringes the patents-in-suit ("for the use in treating or preventing age-related eye disease or for maintaining or preserving eye health or vision, which infringe the claims of the [patents-in-suit]"), and that Defendant knew of the patents-in-suit and intentionally caused and induced its customers to infringe by selling the compositions with promotions and instructions for use. (D.I. 1 ¶¶ 15, 16, 28, 29) Plaintiffs also allege that Defendant "is selling offering for sale and/or importing components or materials, knowing the same to be especially made or especially adapted for use in an infringement" of the patents-in-suit. (*Id.* ¶¶ 14, 17, 27, 30) These facts, accepted as true and viewed in the light most favorable to Plaintiffs, are adequate to support plausible claims of indirect infringement. *See, e.g., In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1341-42 (Fed. Cir. 2012) (finding that advertising of product's benefits gives rise to reasonable inference of intention to induce customers to accomplish these benefits through utilization of patented method).

Defendant's remaining arguments focus on the merits, not the adequacy, of Plaintiffs' infringement claims, and do not provide a basis for granting dismissal. Defendant contends that Plaintiffs cannot plausibly allege literal infringement because the vitamin C content of the accused products is above the maximum vitamin C content claimed in the patents-in-suit. (*See*

Additionally, again in *Bot M8*, the Federal Circuit affirmed the district court's finding that the plaintiff failed to state an infringement claim because the plaintiff failed to allege that "the game program and mutual authentication program are stored **together**." *Id.* at 1354-55. The Federal Circuit observed that "[w]hile [the plaintiff] points to different storage components in the allegedly infringing devices, it never says which one or ones satisfy the mutual authentication limitation." *Id.* at 1355. Here, by contrast, the complaint identifies the accused products and explicitly alleges that the compositions of the accused products satisfy the claimed formulation of the asserted patents.

D.I. 9 at 6, 16) Defendant further insists that Plaintiffs' reliance on the doctrine of equivalents is precluded by prosecution history estoppel. (*See id.* at 6-13) Defendant's theory of no literal infringement, however, requires the Court to consider materials outside of the pleadings and perform an early claim construction, practices either unpermitted or unwarranted at the motion to dismiss stage.²

Defendant asks the Court to consider the labels of the accused products and accept the facts described thereon – that the vitamin C content of the accused products is 750 mg – as true. (*See id.* at 16-17) The labels of the accused products are not part of the pleadings and Defendant has not cited authority permitting the Court to consider their contents in connection with the pending motion. The accused products' vitamin C content is not subject to judicial notice, because whether the labels accurately represent the actual vitamin C content of the accused products – although a proposition supported by a declaration of one of Defendant's employee (*see* D.I. 11) – may be reasonably disputable. Nor will the Court consider the product labels under the incorporation-by-reference doctrine, as the labels are not "***integral to or explicitly relied*** upon in the complaint." *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (emphasis added).

In any event, even assuming the accused products' vitamin C content is 750 mg, whether that amount falls outside of the claimed range requires claim construction, as the plain text of the claimed range – "approximately 7 to 10 times the RDA" – recites no absolute amounts.

² Defendant repeatedly asserts that Plaintiffs have "concede[d]" there can be "no literal patent infringement." (*See, e.g.*, D.I. 14 at 4, 6) The record reveals no such concession. Plaintiffs state that "to the extent the amount of vitamin C in the accused products does not fall within the literal scope of the vitamin C limitations of the Patents-in-Suit," it is insubstantially different from the claimed range of vitamin C (D.I. 13 at 17 n.4), which suggests infringement by equivalents but no abandonment of literal infringement.

Defendant's contention that the patent specification "confirms the equivalence of 7 to 10 times RDA with 420 to 600 mg" because "the range cannot 'float' over time with changes in RDA" is an argument that may be suitable for claim construction (*see D.I. 9 at 7*), but is not appropriately resolved at the pleading stage. (*See D.I. 13 at 14; see also Nalco*, 883 F.3d at 1349; *Boston Fog, LLC v. Ryobi Techs., Inc.*, 2020 WL 1532372, at *4 (D. Del. Mar. 31, 2020); *Innovative Global Sys., LLC v. Keep Truckin, Inc.*, 2020 WL 1443201, at *7 (D. Del. Mar. 24, 2020); *Par Pharm., Inc. v. Hospira, Inc.*, 2018 WL 3343238, at *4 (D. Del. May 11, 2018))

B. Motion For A More Definite Statement

Alternatively, Defendant contends that Plaintiff should be ordered to provide a more definite statement "to adequately apprise [D]efendant of the factual basis" of Plaintiffs' infringement claims. (D.I. 9 at 17) But the complaint is not "so vague or ambiguous" that it prevents Defendant from reasonably preparing a response. *See Fed. R. Civ. P. 12(e)*. As already explained, the factual allegations of the complaint provide Defendant with adequate notice as to accused infringement. Accordingly, the Court will deny Defendant's alternative request for a more definite statement pursuant to Rule 12(e).

IV. CONCLUSION

For the foregoing reasons, the Court will deny Defendant's motion to dismiss. The Court will also deny Defendant's alternative request for a more definite statement. An appropriate order follows.